PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

24 JUN 2004

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
P1714PC00		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NO 2002/000498	27.12.2002	27.12.2001
International Patent Classification (IPC) or national classification and IPC		
A61B 5/11 // A61B 5/02		
Applicant		
Medinnova SF et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.06.2003	12.02.2004
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Johanna Schyberg /OGU Telephone No. +46 8 782 25 00

Form PCT/IPEA/409 (cover sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NO 2002/000498

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☒ This report is based on a translation from the original language into the following language English, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☒ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-17 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 19-21 received by this Authority on 06.02.2004
pages* _____ received by this Authority on _____

☒ the drawings:

pages 1-19 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NO 2002/000498

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-22	YES
	Claims	---	NO
Inventive step (IS)	Claims	1-22	YES
	Claims	---	NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims	---	NO

2. Citations and explanations (Rule 70.7)

Prior art

In the international search report the following documents were cited:

D1: US5109842 A
D2: US5628777 A
D3: Rickards, A.F. et al "An Implantable Intracardiac Accelerometer for monitoring Myocardial Contractility"
D4: John C. Wood et al, "Time Frequency transforms: A New Approach to First Heart Sound Frequency Dynamics"
D5: US5161540 A
D6: US 4204544 A

D1 discloses a tachyarrhythmia control system provided with a patch electrode having a motion sensor integrated in the patch electrode. The patch electrode is attached to cardiac tissue, such as by placement directly on the myocardial surface, or the pericardial sac, so that wall motion of the cardiac muscle can be evaluated, see column 2 lines 2-8.

D2 also relates to implantable cardiac stimulating devices incorporating accelerometer-based cardiac wall motion sensors. The cardiac wall motion sensors transduce accelerations of cardiac tissue to provide electrical signals indicative of cardiac wall motion to an implantable cardiac stimulating device.

D3 shows a microaccelerometer located inside the tip of an otherwise conventional pacing lead.

D4 shows a study, where cardiac vibrations were recorded using an ultralight accelerometer cemented directly to the epicardium of the anterior left ventricle.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V.

D5 discloses a device for monitoring a patient for rejection reactions of an implanted heart, by a permanent magnet implanted in the heart wall and a magnetically active semiconductor element, preferably a Hall generator, implanted endocardially.

D6 discloses a myocardial transducer for simultaneously measuring force and displacement within a very small area of myocardium. The transducer includes a piezoresistive element. Thin insulated leads are connected to instrumentation for displaying and/or recording the displacement signal from the piezoresistive element, see column 4 lines 4-15.

Statement of reason

The claimed invention discloses a method and a system for calculating abnormalities in the heart, e.g. ischemia, from a signal recorded by a sensor system, which is fitted to the surface or immediately below the outer surface of the heart muscle. The recorded signal reflects the movements of the heart wall, e.g. after an operation. The invention also includes a sensor for recording said signal.

D1 to D3, which all show pacemaker electrodes equipped with a sensor, similar to what is referred to on page 2 of the description, are considered to state the closest prior art of the invention.

The invention claimed in claim 1 differs from this prior art in that the abnormalities are detected from a signal describing the movements of the heart wall.

By using a signal describing the movements of the heart wall, it is possible to measure the contractility of the heart muscle in specific areas as a function of blood supply. It has been discovered that a change in the frequency distribution or amplitude of the signal indicates abnormal heart activity. Such a solution to the problem of detecting abnormalities in the heart has not been found in the international search. Hence, the invention claimed in claims 1-22 is novel, and is considered to involve an inventive step.

The invention is industrially applicable.

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DT09 Rec'd PCT/PTO 24 JUN 2004

Claims

1. Method for calculating changes in movement of the heart, e.g. related to ischemia, from a signal describing the acceleration of the heart wall, which is recorded by a motion sensor fastened to a selected position on the surface of an active heart, by detecting patterns in said recorded signal that deviate from the pattern of normal activity, wherein said sensor registers the movements of the heart in this position in three directions.

2. Method according to claim 1, wherein the method is performed post-operatively in connection with a bypass operation.

3.. Method according to claim 1, wherein the position is selected as a central point of that part of the heart muscle which after an operation receives blood from the revascularised coronary artery.

4. Method according to claim 1, wherein the motion sensor is designed by means of its dimensions and fastening devices to be removable from the position without requiring surgical intervention.

5. Method according to claim 1, wherein the motion sensor comprises an accelerometer that is sensitive to acceleration in three directions.

6. Method according to claim 1, wherein the motion sensor comprises a gyroscope for measuring rotary movement at the point of attachment of the sensor.

7. Method according to claim 1, wherein the registered movement is transmitted to a calculation unit located externally of the patient for performing said analysis..

8. Method according to claim 1, wherein the motion sensor is incorporated into a temporary pacemaker electrode.

9. A motion sensor for registering the movements of a heart wall, which sensor is a sensor with a sensitivity in three directions and is provided with external material that does not cause reactions in biological material and devices for fasting to a selected position on the surface of the heart, which sensor furthermore comprises a signal conductor for transmitting registered information to a calculation unit located externally of the patient.

10. A motion sensor for registering the movements of a heart, which sensor is a motion sensor with a sensitivity in three directions of at least 600mV/g within a frequency range of 200Hz (band width) with a maximum amplitude of 2.5V, has dimensions of less than 1.5x1.5x4mm and is provided with an external material that does not cause reactions in biological material, and devices for fastening to a selected position on the surface of the heart, which sensor furthermore comprises a signal conductor for transmitting registered information to a calculation unit located externally of the patient .

11. A motion sensor according to Claim 9 or 10, characterised in that the dimensions of the sensor are less than 1x1x2mm.

12. The motion sensor according to any of the Claims 9 to 11, characterised in that the sensor is integrated into a temporary pacemaker electrode.

13. A motion sensor according to any of the Claims 9 to 12, characterised in that it comprises an accelerometer having three directions of sensitivity.

14. A motion sensor according to any of the claims Claim 9 to 13, characterised in that it comprises a gyroscope for measuring rotary movement about at least one axis at the selected point.

15. A system for detecting changes in the movement of the heart, e.g. related to ischemia, comprising at least one motion sensor according to any of the Claims 9 to 14, where the sensor is designed to be fastened to the surface of a heart and where the sensor is designed to emit signals that reflect the heart activity to a calculation unit, said

calculation unit being adapted to analyze the registered movements and detecting changes in the pattern of the movements of the heart in the position of the sensor.

16. A system according to Claim 15, characterised in that it further includes biosensors that integrated into the accelerometer or fixed to a pacemaker electrode in order to emit signals that are characteristic to the heart activity.

17. A system according to Claim 15 or 16, characterised in that it further includes an amplifier and a calculation unit designed to amplify and calculate the signals, and a device for indicating deviation upon comparison.

18. A system according to Claim 17, characterised in that the calculation unit is expected to use fast Fourier transform for determining the frequency distribution.

19. A system according to Claim 17, characterised in that the calculation unit determines the frequency distribution of the signals, and that these are compared with a pre-set standard distribution.

20. A system according to Claim 17, characterised in that the pre-set standard distribution employed is the frequency distribution calculated immediately after insertion of the sensor.

21. A system according to Claim 20, characterised in that it comprises a device for indicating deviation from predetermined values, comprising an alarm transmitter designed to emit an alarm signal when the deviation from said standard distribution exceeds a certain level.

22. A system according to Claim 15, characterised in that the motion sensor is incorporated into a temporary pacemaker electrode.